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Comparing oral and intravenous paracetamol plasma levels when given as pre-medication for peri-operative analgesia

Submission date	Recruitment status	[_] Prospectively registered
19/06/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/11/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/03/2013	Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

06/Q2002/25

Study information

Scientific Title

Acronym
Paracetamol

Study objectives
The hypothesis is that in the peri-operative setting gastric emptying is delayed and that the absorption of oral paracetamol preparation is therefore unreliable. It might be more appropriate to use the intravenous route and if so will become apparent during the study.

The aim of this research study is to compare plasma levels of the intravenous and oral paracetamol preparations when used as pre-emptive analgesia. We wish to establish whether the intravenous preparation, the oral preparation or both achieve therapeutic plasma levels intra-operatively. Use of paracetamol as a pre-emptive analgesia is well established in previous studies, which have shown that pre-emptive analgesia reduces post-operative pain more than when analgesia is used solely post-operatively and others have shown that peri-operative use of paracetamol also reduces opioid use.

Therefore, is intravenous paracetamol more effective than the oral preparation when given as a pre-medication?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Peri-operative analgesia

Interventions
Group A: Intravenous injection equivalent to one gram paracetamol given by the researchers immediately prior to induction of anaesthesia in theatre.
Group B: One gram oral paracetamol prescribed on the ward and given by the nursing staff or researchers one to two hours before induction of anaesthesia.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Paracetamol

Primary outcome measure
Therapeutic plasma level of paracetamol (when the plasma level is 10 - 20 mg/l [the test will be at 30 minutes post induction of anaesthesia])

Secondary outcome measures
Non-therapeutic plasma level of paracetamol

Overall study start date
01/08/2006

Completion date
01/08/2007

Eligibility

Key inclusion criteria
1. Assessment of fitness as indicated by the American Society of Anesthesiologists (ASA) grades I and II
2. Age group 16 to 75 years
3. All patients listed for elective surgery by Mr P Robinson on a Thursday for Ear, Nose & Throat surgery

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants

104 (52 in each group)

Key exclusion criteria
1. Patients refusing to participate in study
2. Patient unable to take an oral preparation
3. Cases shorter than one hour
4. Patients already taking a paracetamol containing drug combination, or have taken in the last 12 hours
5. Patients with a history of paracetamol allergy, hypersensitivity or previous reaction/serious adverse reaction
6. Children under the age of 16
7. Patients unable to understand or give consent to participation in the study; incapable adults, psychiatric/medical disorder able to modify patient compliance
8. Pregnant or breastfeeding
9. History of complete non-responsiveness to acetaminophen
10. Pancreatic disease in the previous 12 months
11. Impaired liver/kidney function
12. Patients that might pose an infection risk to staff due to blood products

Date of first enrolment
01/08/2006

Date of final enrolment
01/08/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Consultant Anaesthetist
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Sponsor information

Organisation
North Bristol NHS Trust (UK)

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Sponsor type
Hospital/treatment centre

Website
http://www.nbt.nhs.uk/

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Government

Funder Name
North Bristol NHS Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2011		Yes	No